# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

OSBAKKEN et al.

Serial No.

09/942,959

Filed:

August 31, 2001

AEROSOLIZED ANTI-INFECTIVES.

**ANTI-INFLAMMATORIES, AND DECONGESTANTS FOR THE** TREATMENT OF SINUSITIS

Confirmation No.: 7962

1616

Art Unit: Examiner:

Dewitty, R.

### TRANSMITTAL LETTER

Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Sir:

Transmitted herewith via hand delivery are a Supplemental Information Dis Statement, Form PTO-1449 (9 pages) and cited references for filing in connection with the above-identified application.

[X] The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,

HELLER, EHRMAN, WHITE & MCAULIFFE LLP

By:

Dale L. Rieger

Registration No. 43,045

April 14, 2003

Attorney Docket 39187-1457

Address all correspondence to:

Stephanie L. Seidman

HELLER EHRMAN WHITE & McAULIFFE LLP

4350 La Jolla Village Drive, 7th Floor

San Diego, California 92122-1246

Telephone: (858) 450-8400

Facsimile: (858) 587-5360

E-mail: sseidman@HEWM.com

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# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Since this Supplemental Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (9 pages) and the cited references are provided herewith.

The documents listed on the Form PTO-1449 and supplied herewith are in the English language, with the exception of Items BG, BI, BQ, CQ and CS. A certified English-language translation of Item BG is provided (Item CE). EnglishU.S.S.N. 09/942,959 Osbakken *et al.* Supplemenatal Information Disclosure Statement

language Derwent abstracts for Items BI and BQ are provided (Items CI and CJ, respectively). English-language abstracts are provided on the last page of Items CQ and CS. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. and International applications, which are commonly owned and/or have one or more inventors in common.

<u>U.S.S.N.</u>	Filing Date	Docket No.	<u>Status</u>
09/577,623	05/25/02	1456	Allowed
10/193,081	07/09/02	1456B	Pending
10/231,804	08/28/02	. 1456C	Pending
Int'l App. no.	Filing Date	Docket No.	
PCT/US02/27868	08/31/01	1457PC	

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

U.S.S.N. 09/942,959 Osbakken et al. Supplemenatal Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

> Respectfully submitted, HELLER EHRMAN WHITE & McAULIFFE LLP

By:

Dale L. Rieger

Registration No. 43,045

April 14, 2003

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Address all correspondence to:

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Telephone: (858) 450-8400

Facsimile: (858) 587-5360 E-mail: sseidman@HEWM.com

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STATEMENT	FILING DATE August 31, 2001	GROUP 1616	15 P	RECEN

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## **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	*Ref. Code		D	OCUM	IENT I	NUMB	ER		DATE	NAME	CLASS	SUB CLASS	FILING DATE
	A	0	0	5	2	3	3	8	05/02/02	Yerxa et al.	514	47	12/03/01
	В	0	0	6	5	2	4	4	05/30/02	Yerxa et al.	514	47	11/09/01
	С	0	1	0	3	1	5	7	08/01/02	Yerxa <i>et al</i> .	514	47	01/03/02
	D	4	3	1	2	8	6	0	01/26/82	Clements	424	199	10/24/80
	E	4	3	5	5	0	2	1	10/19/82	Mahi et al.	424	28	10/29/80
	F	4	4	2	4	2	1	6	01/03/84	Cerami et al.	424	211	07/31/79
	G	4	4	6	8	5	1	3	08/28/84	Kirst <i>et al</i> .	536	16.8	09/07/82
	Н	4	4	7	8	8	2	2	10/23/84	Haslam et al.	424	78	05/16/83
	1	4	4	8	6	4	1	8	12/04/84	Watanabe <i>et al.</i>	424	180	06/06/83
	J	4	4	9	3	8	3	1	01/15/85	Takaya <i>et al.</i>	424	180	09/30/83
	К	4	5	5	4	2	6	9	11/19/85	Takaya <i>et al.</i>	514	35	01/24/84
	L	4	5	7	1	3	3	4	02/18/86	Yoshida et al.	424	95	12/04/91
	М	4	5	9	3	0	8	9	06/03/86	Wang et al.	536	13.6	10/31/83
	N	4	6	1	7	2	9	3	10/14/86	Wahlig <i>et al.</i>	514	41	05/23/84
· <del></del>	0	4	6	4	7	6	5	6	03/03/87	Watanabe et al.	536	16.1	08/14/84
	Р	4	6	5	6	1	6	0	04/07/87	Takaya <i>et al.</i>	514	41	11/18/85
	Q	4	6	8	4	6	4	3	08/04/87	Buddenbaum et al.	514	204	06/03/85
	R	4	7	4	9	7	0	0	06/07/88	Wenig	514	225.2	04/24/87
	S	4	8	5	5	2	8	7	08/08/89	Watanabe et al.	514	41	09/03/86
	T	4	9	0	6	4	7	6	03/06/90	Radhakrishnan	424	450	12/14/88
<del></del>	U	5	0	0	4	6	1	1	04/02/91	Keigh	424	450	03/21/88

**EXAMINER** 

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	٧	5	0	0	6	3	4	3	04/09/91	Benson et al.	424	450	12/29/88
	W	5 .	0	3 .	9	6.	6	6	08/13/91	Novick, Jr.	517	37	10/30/90
	х	5	0	4	9	3	8	8	09/17/91	Knight <i>et al</i> .	424	450	07/21/89
	Υ	5	0	4	9	3	8	9	09/17/91	Radhakrishnan	424	450	12/01/89
	Z	5	1	1	٥	8	0	6	05/05/92	Clements	514	78	04/07/89
	AA	5	1	- 1	2	8	0	4	05/12/92	Kowarski	514	3	09/14/89
	AB	5	1	4	1	6	7	4	08/25/92	Keigh	252	305	06/24/91
	AC	5	1	6	7	5	0	6	12/01/92	Kilis et al.	434	262	10/24/91
	AD	5	1	6	9	6	3	7	12/08/92	Kenk et al.	424	450	04/02/91
	AE	5	2	9	9	5	6	6	04/05/94	Davis et al.	128	200	09/18/92
	AF	5	5	0	8	2	6	9	04/16/96	Smith <i>et al</i> .	514	38	10/19/94
	AG	5	5	1	2	2	6	9	04/30/96	Molina y Vedia et al.	424	45	06/09/93
	АН	5	5	2	2	3	8	5	06/04/96	Lloyd et el.	128	203.26	09/27/94
	Al	5	5	2	5	3	2	9	06/11/96	Snyder et al.	424	45	01/03/95
	AJ	5	5	6	7	7	1	6	10/22/96	Della Valle et al.	514	332	11/19/93
	AK	5	5	9	5	9	7	7	01/21/97	Dyrsting et al.	514	39	10/27/93
	AL	5	6	1	4	2	1	6	03/25/97	Janoff	424	450	05/16/95
	AM	5	6	2	4	9	6	2	01/21/97	Dyrating <i>et al.</i>	514	39	10/27/93
	AN	5	6	5	5	5	2	3	08/12/97	Hodson <i>et al.</i>	128	315	05/22/95
	AO	5	6	8	5	2	9	1	11/11/97	Marsh	128	200.15	11/15/96
	AP	5	8	6	1	2	7	5	01/19/99	Hansen	435	69.1	09/28/95

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	AQ	5	8	9	7	8	7	2	04/27/99	Picciano	424	434	11/12/97
	AR	5	9	0	0	4	0	6	05/04/99	von Ahsen et al.	514	35	06/08/94
	AS	5	9	٥	0	4	0	7	05/04/99	Yerxa et al.	514	47	02/06/97
	AT	5	9	0	6	1	9	8	05/25/99	Flickinger	128	200.21	07/14/97
	AU	5	9	8	5	2	5	9	11/16/99	Cagle et al.	424	78.04	04/30/97
_	AV	6	0	3	7	3	5	8	03/14/00	Gordziel	514	357	03/24/9
	AW	6	0	8	3	9	2	2	07/04/00	Montgomery	514	38	04/02/9
	AX	6	2	4	1	9	6	9	06/05/01	Saidi et al.	424	45	06/26/9
·	AY	6	2	7	7	8	5	5	08/21/01	Yerxa	514	256	04/21/00
	AZ	6	3	3	1	5	2	9	12/18/01	Yerxa <i>et al.</i>	514	47	02/25/00
	BA	6	3	8	7	8	8	6	B1 05/14/02	Montgomery et al.	514	34	11/28/0
	BB	6	4	2	0	3	4	7	07/16/02	Jacobus <i>et al.</i>	514	51	07/17/98
	ВС	6	4	2	3	6	9	4	07/23/02	Drutz et al.	514	51	02/21/9
	BD	6	4	3	6	9	1	0	08/20/02	Yerxa <i>et al</i> .	514	47	12/03/0
	BE	6	4	4	8	2	7	6	09/10/02	Yerxa	514	357	05/17/0
	BF	6	4	6	2	1	8	3	10/08/02	Toth et al.	536	17.2	08/26/99

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUB CLASS	Trans Yes	No No
	BG	1	0	1	3	0	1	48	05/19/9B	JP (A)			×	
	ВН	0	4	7	0	1	5	4	06/05/96	EP (B1)				

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EXAMINER INITIAL	*Ref. DOCUMENT NUMBER Code						ER		DATE	COUNTRY	CLASS	SUB CLASS	Trans Yes	No No
· · · · · · · · · · · · · · · · · · ·	BI	0	5	0	7	7	0	7	07/12/95	EP (B1)				+X
	BJ	0	5	6	3	1	3	. 1	09/11/96	EP (B1)				
	BK	0	6	8	2	5	1	4	09/12/01	EP (B1)				
	BL	0	7	0	5	6	1	4	09/25/02	EP (B1)				
	ВМ	o	9	2	5	3	0	8	06/02/02	EP (81)		<u>.</u>		
	BN	0	0	0	0	1	8	1	01/06/00	PCT (A1)				
	во	0	0	5	0	0	2	4	08/31/00	PCT (A2, A3)				
	ВР	0	1	0	2	0	2	4	01/11/01	PCT (A1)				
	BQ	٥	1	1	9	3	4	4	03/22/01	PCT (A1)				+X
	BR	0	1	8	0	8	4	4	11/01/01	PCT (A2, A3)				
·	BS	0	2	0	6	8	0	31	09/06/02	PCT (A2)				
	вт	9	7	2	9	7	5	6	08/21/97	PCT (A1)			<u> </u>	
<del></del> -	BU	9	7	3	5	5	9	1	10/02/97	PCT (A2, A3)				
	B∨	9	8	3	4	5	9	3	08/13/98	PCT (A1)		<u> </u>		

# OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BW	Adelroth et al., "Airway responsiveness to leukotrienes C <sub>4</sub> and D <sub>4</sub> and to methacholine in patients with asthma and normal controls", N Engl J Med, 315:480-484 (1986)
вх	Alexandrakis et al., "Nasolacrimal Duct Obstruction and Orbital Cellulitis Associated With Chronic Intranasal Cocaine Abuse," Arch Ophthalmol, 117:1617-1622 (1999)
BY	Baraniuk et al., "Addition of intranasal glucocorticoids to standard antibiotic therapy for sinusitis", Current Allergy and Asthma Rep, 1(3):191-192 (2001)

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	<u> </u>
BZ	Bell et al., "A-78773: a selective, potent 5-lipoxygenase inhibitor", J Lipid Mediators, 6:259-264 (1993)
CA	Bhattacharyya et al., "The Microbiology of Recurrent Rhinosinusitis After Endoscopic Sinus Surgery", Arch Otolaryngol Head Neck Surg, 125(10):1117-1120 (1999)
СВ	Boner et al., "A combination of cefuroxime and N-acetyl-cysteine for the treatment of maxillary sinusitis in children with respitatory allergy", Int J Clin Pharmacol Ther Toxicol, 22(9):511-514 (1984)
СС	Boyce et al., "MRSA patients: proven methods to treat colonization and infection," Journal of Hospital Infection, 48(Supplement A):S9-S14 (2001)
CD	Braun et al., "Adjunct effect of loratedine in the treatment of acute sinusitis in patients with allergic rhinitis", Allergy, 52(6):650 (1997)
CE	Certified English Translation for Japanese Patent Application (Kokai) No. 10-130148 entitled: "Composition for Nebulizers".
CF	Cimochowski et al., "Intranasal Mupirocin Reduces Sternal Wound Infection After open Heart Surgery in Diabetics and Nondiabetics," Ann Thorac Surg, 71:1572-1579 (2001)
CG	Cohen, M.L., "Antimicrobial resistance: prognosis for public health", <i>Trends Microbiol</i> , 2:422-425 (1994)
СН	Dahlen et al., "Leukotrienes are potent constrictors of human bronchi", Nature, 288:484-486 (1980)
CI	Derwent# 009206491, W.P.I. Acc No: 1992-333912/199241, for European Patent Application, EP 507707 A, "Control unit for therapeutic nebuliser - has sonic vibration control chamber made separate from over-pressure control chamber and linked to pulsed air source".
C1	Derwent# 013773627, W.P.I. Acc No.: 2001-257838/200126, for PCT Patent Application, WO 200119344 A1, "Preparing powders for nasal atomization, useful e.g. for administering Vitamin B12, using water insoluble, absorbent excipient to carry active ingredient".

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0.	THER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
СК	Desrosiers et al., "Treatment of chronic rhinosinusutus refractory to other treatments with topical antibiotic therapy delivered by means of a large-particle nebulizer: Results of a controlled trial," ArchOtolaryngol Head Neck Surg, 125:265-269 (2001)
CL	Dolor et al., "Comparison of Cefuroxime With or Without Intranasal Fluticasone for the Treatment of Rhinosinusitis," <i>J Am Med Assoc</i> , 286:3097-3105 (2001)
СМ	Dunbar, C.A. and A.J. Hickey, "Evaluation of Probability Density Functions To Approximate Particle Size Distributions of Representative Pharmaceutical Aerosols," <i>J Aerosol Sci</i> , 31(7):813-831 (2000)
CN	Etkins et al., "Sinusitis", Nidus Information Services, Inc. Well-Connected Report #62: Sinusitis, www.well-connected.com (2002)
СО	Farr, B.M., "Mupirocin to Prevent S. <i>Aureus</i> Infections," <i>N.E. J Med</i> , 346(24):1905-1906 (2002)
СР	Gürses et al., "Cefuroxime axetil in the treatment of acute sinusitis in childhood", J Antimicrob Chemother, 38:547-550 (1996)
ca	Hiramatsu et al., "MRSA Infections in an Intensive Care Unit," Masui, 49:867-871 (2000)
CR	Hitomi et al., "Control of a methicillin-resistant Staphylococcus aureus outbreak in a neonatal intensive care unit by unselective use of nasal mupirocin ointment," J Hosp Infec, 46:123-129 (2000)
CS	Holmström, M., "Nasal polyposis - of interest to several specialities. Improvements in diagnosis and new treatment methods," <i>Lakartidningen</i> , 97(34):3611-3615 (2000)
ст	Jeong et al., "Intranasal mupirocin for prevention of hospital MRSA infection," ASHP-Mid-year Clin Mtg, Abstract of Meeting Presentation, 33(Dec):INTL-21 (1998)
cu	Kaiser et al., "Impact of Zanamivir on Antibiotic Use for Respiratory Events Following Acute Influenza in Adolescents and Adults," Arch Intern Med, 160:3234-3240 (2000)
cv	Knowles, S., "Five-day otitis media therapy. Cisapride monitoring in children. Efficacy of sumatriptan nasal spray. Testosterone for AIDS wasting.," <i>Pharm Prac</i> , (Canada) 14:28-30 (1998)
cw	Koltai et al., "Pseudomonas Aeruginosa In Chronic Maxillary Sinusitis", Laryngoscope, 95:34-37 (1985)

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•	
сх	Lane et al., "Leukotriene antagonism in asthma and rhinitis", Respir Med, 92:795-809 (1998)
CY	Lim et al., "In vivo evaluation of novel hyaluronan/chitosan microparticulate delivery systems for the nasal delivery of gentamicin in rabbits," Intern J Pharm, 231:73-82 (2002)
CZ	Maccabee, M. and P.H. Hwang, "Medical Therapy of Acute and Chronic Frontal Rhinosinusitis," <i>Otolaryngol Clin N. Am</i> , 34:41-47 (2001)
DA	Mahajan et al., "Intranasal Administration of Fusidic Acid Cream in Leprosy," Indian J Leprosy, 72(4):451-455 (2000)
DB	McMillan et al., "Designing therapeutically effective 5-lipoxygenase inhibitors", Trends Pharmacy Sci, 13:323-330 (1992)
DC	Meltzer et al., "Added relief in the treatment of acute recurrent sinusitis with adjunctive mometasone furoate nasal spray," J Allergy Clin Immunol, 106:630-637 (2000)
DD	Nagl et al., "Activity of N-chlorotaurine against herpes simplex- and adenoviruse", Antiviral Res, 38:25-30 (1988)
DE	Nagl et al., "Bactericidal Activity of Micromolar N-Chlorotaurine: Evidence for Its Antimicrobial Function in the Human Defense System", Antimicrobial Agents and Chemotherapy, 44(9):2507-2513 (2000)
DF	Nardi et al., "Reduction in Gram-positive pneumonia and antibiotic consumption following the use of a SDD protocol including nasal and oral mupirocin," Eur J Emergency Med, 8:203-214 (2001)
DG	Neher et al., "N-Chlorotaurine, a Novel Endogenoius Antimicrobial Agent", 127:530-533 (2001)
DH	Nichol et al., "Effectiveness of Live, Attenuated Intranasal Influenza Virus Vaccine in Healthy, Working Adults," <i>J Am Med Assoc</i> , <u>282(2)</u> :137-144 (1999)
DI	Oszi et al., "Quantitative determination of polysorbate 20 in nasal pharmaceutical preparations by high-performance liquid chromatography", 18:715-720 (1998)
DJ	Package Insert for: Proventil® (brand of albuterol sulfate), Schering Corporation, 1986

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# DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>+</sup> Derwent English language abstract and/or English translation provided.

FORM PTO-1449	ATTY. DOCKET NO. 39187-1457	SERIAL NO. 09/942,959
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE	APPLICANT OSBAKKEN et al.	
STATEMENT	FILING DATE August 31, 2001	GROUP 1616

<sup>\*</sup> If an asterisk is placed beside the reference number, a copy is NOT provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filling date under 35 U.S.C. 120. 37 C.F.R. § 1.98(d).

01	HER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
DK	Package Insert for: Pulmicort Respules™ (Budesonide inhalation suspension), AstraZeneca, 2000
DL	Package Insert for: Pulmicort Turbuhaler 200 mcg (Budesonide inhalation powder), AstraZeneca, 2001
DM	Press Release, "Atlantic Technology Ventures, Inc. Licenses World Wide Rights to ATV-02 Antimicrobial Agent", Atlantic Technology Ventures, pgs 1-3, http://biz.yahoo.com/bw/020709/92194_1.html (2002)
DN	Perkins et al., "Hemothorax in 2 Horses," J Vet Intern Med, 13:375-378 (1999)
DO	Perl et al., "Intranasal Mupirocin to Prevent Postoperative Staphylococcus Aureus Infections," N.E. J Med, 346(24):1871-1877 (2002)
DP	Raikhlin-Eisenkraft, B. and Y. Bentur, "Ecbalium elaterium (Squirting Cucumber)- Remedy or Poison," Clin Toxicol, 38(3):305-308 (2000)
DQ	Reicin et al., "Montelukast, a Leukotriene Receptor Antagonist, in Combination With Loratadine, a Histamine Receptor Antagonist, in Combination With Loratadine, a Histamine Receptor Antagonist, in the Treatment of Chronic Asthma", Arch Intern Med, 160:2481-2488 (2000)
DR	Reiss et al., "Montelukast, a Once-Daily Leukotriene Receptor Antagonist, in the Treatment of Chronic Asthma", Arch Intern Med, 158:1213-1220 (1998)
DS	Reiss et al., "Montelukast (MK-0476), A CysLT, Receptor Antagonist, Improves Asthma Outcomes Over a 3-month Treatment Period", Am J Respir Crit Care Med, 15(5):A662 (1997)
DT	Reiss et al., "MK-0476, An LTD <sub>4</sub> Receptor Antagonist, Improves the Signs and Symptoms of Asthma with a Dose as Low as 10 mg, Once Daily", Am J Respir Crit Care Med, 151:A378 (1995)
DU	Reiss et al., "MK-0476, AN LTD <sub>4</sub> Receptor Antagonist, Exhibits a Dose Related Improvement in the Once Daily Treatment of Patients with Chronic Asthma", Eur Respir J, 19(suppl):289S (1995)
 <u> </u>	

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	DV	Seggev et al., "A Combination of Amoxicillin and Clavulanate Every 12 Hours vs Every 8 Hours for Treatment of Acute Bacterial Maxillary Sinusitis", Arch Otolaryngol Head Neck Surg, 124:921-925 (1998)
2	DW	Smith et al., "The Effect of Inhaled Leukotriene D4 in Humans <sup>1-3</sup> ", Am Rev Respir Dis, 131:368-372 (1985)
	DX	Tracy et al., "Intranasal beclomethasone as an adjunct to treatment of chronic middle ear effusion, Annals of Allergy, Asthma Immunol, 80:198-206 (1998)
	DY	Tradename: ATV-02, "BioSpace Clinical Development: ATV-02 Detail", <i>Atlantic Technology Ventures</i> , http://www.biospace.com/ccis/detail.cfm?Clinical1ID = 794920 (2002)
	DZ	Tsurita et al., "Early Augmentation of Interleukin (IL)-12 Level in the Airway of Mice Administered Orally with Clarithromycin or Intranasally with IL-12 Reults in Alleviation of Influenza Infection," <i>J Pharmacol Exper Therap</i> , 298(1):362-368 (2001)
	EA	Waltimo et al., "In Vitro susceptibility of Candida albicans to four disinfectants and their combinations", Int Endod J, 32:421-429 (1999)
	EB	Wang, J. and G. Bu, "Influence of intranasal medication on the structure of the nasal mucosa, <i>Chinese Med J</i> , 115(4):617-619 (2002)
	EC	Wang, J. and G. Bu, "Influence of the nasal mucociliary system on intranasal drug administration," <i>Chinese Med J</i> , 113(7):647-649 (2000)
	ED	Yilmaz et al., "Intranasal budesonide spray as an adjunct to oral antibiotic therapy for acute sinusitis in children," Eur Arch Otorhinolaryngol, 257:256-259 (2000)

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